

## PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

REC'D 27 AUG 2004



WIPO PCT

Applicant's or agent's file reference 031571woMetg	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/EP 03/06799	International filing date (day/month/year) 27.06.2003	Priority date (day/month/year) 28.06.2002
International Patent Classification (IPC) or both national classification and IPC A61K39/095		
Applicant BRAUN, Jan Matthias ET AL.		

1. This International preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets, including this cover sheet.
  - ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 3 sheets.

3. This report contains indications relating to the following items:
  - I ☒ Basis of the opinion
  - II ☐ Priority
  - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
  - IV ☐ Lack of unity of invention
  - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
  - VI ☐ Certain documents cited
  - VII ☐ Certain defects in the international application
  - VIII ☐ Certain observations on the international application

Date of submission of the demand  27.01.2004	Date of completion of this report  23.08.2004
Name and mailing address of the International preliminary examining authority:   European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer  Noë, V  Telephone No. +31 70 340-4181  

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International application No. **PCT/EP 03/06799**

**I. Basis of the report**

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*):

**Description, Pages**

1-56 as originally filed

**Claims, Numbers**

1-12 filed with telefax on 14.07.2004

**Drawings, Sheets**

1/12-12/12 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).  
☐ the language of publication of the international application (under Rule 48.3(b)).  
☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.  
☐ filed together with the international application in computer readable form.  
☐ furnished subsequently to this Authority in written form.  
☐ furnished subsequently to this Authority in computer readable form.  
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.  
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:  
☐ the claims, Nos.:  
☐ the drawings, sheets:

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5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Yes: Claims	1-12
	No: Claims	
Inventive step (IS)	Yes: Claims	1-12
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-12
	No: Claims	

2. Citations and explanations

**see separate sheet**

**V. Reasoned statement (Continuation)**

**1 CITATIONS**

Reference is made to the following documents:

- D1: JI YIN-DUO ET AL: "The antigen specificity of meningococcal bactericidal antibodies induced by *N. lactamica* and *N. meningitidis*." ZHONGHUA WEISHENGQUXUE HE MIANYIXUE ZAZHI, vol. 14, no. 4, 1994, pages 233-237, XP008013995 ISSN: 0254-5101
- D2: WO 00/50074 A (GORRINGE ANDREW RICHARD ;HUDSON MICHAEL JOHN (GB); IMP COLLEGE SCH) 31 August 2000 (2000-08-31)
- D3: EP-A-0 941 738 (AMERICAN CYANAMID CO) 15 September 1999 (1999-09-15)
- D4: FR-A-2 782 642 (FORCEVILLE XAVIER) 3 March 2000 (2000-03-03)
- D5: GRIFFISS J M ET AL: "Meningococcal molecular mimicry and the search for an ideal vaccine." TRANSACTIONS OF THE ROYAL SOCIETY OF TROPICAL MEDICINE AND HYGIENE. ENGLAND 1991, vol. 85 Suppl 1, 1991, pages 32-36, XP008013992 ISSN: 0035-9203

**2 NOVELTY (Art. 33(2) PCT)**

- 2.1 The subject-matter of claims 1-12 have not been disclosed in the cited prior art and are therefore considered to be novel.
- 2.2 The present application satisfies the criterion set forth in Article 33(2) PCT because the subject-matter of claims 1-12 is new in respect of prior art as defined in the regulations (Rule 64(1)-(3) PCT).

**3 INVENTIVE STEP (Art. 33(3) PCT)**

- 3.1 For inventive step analysis of claim 1, D1 is considered to represent the most

relevant state of the art and discloses the induction of an immune response to *Neisseria meningitidis* serogroup a in mice by LOS from *Neisseria lactamica* (see abstract). The subject-matter of claim 1 differs in that a medicament for the treatment or prevention of *Neisseria meningitidis* infection comprising glycoconjugates and/or lipooligosaccharides (LOS) from *Moraxella catarrhalis* is claimed.

- 3.2 The problem to be solved by the subject matter of claim 1 may therefore be regarded as the provision of an alternative medicament for the treatment or prevention of *Neisseria meningitidis* infection. The solution would be a medicament comprising glycoconjugates and/or lipooligosaccharides (LOS) from *Moraxella catarrhalis*.
- 3.3 This solution is considered as involving an inventive step (Article 33(3) PCT) because the prior art does not disclose nor suggests the use of LOS from *Moraxella catarrhalis* in a medicament for the prevention or treatment of a *Neisseria meningitidis* infection and it would not be obvious for the person skilled in the art to make such a medicament.
- 3.4 For inventive step analysis of claim 3, D1 is considered to represent the most relevant state of the art and discloses the induction of an immune response to *Neisseria meningitidis* serogroup a in mice by LOS from *Neisseria lactamica* (see abstract). The subject-matter of claim 3 differs in that a medicament for the treatment or prevention of *Neisseria meningitidis* infection comprising glycoconjugates and/or lipooligosaccharides (LOS) from *Neisseria lactamica* which are cross-reactive to human blood antigens is claimed.
- 3.5 The problem to be solved by the subject matter of claim 3 may therefore be regarded as the provision of an alternative medicament for the treatment or prevention of *Neisseria meningitidis* infection comprising glycoconjugates and/or lipooligosaccharides (LOS) from *Neisseria lactamica*. The solution would be a medicament comprising glycoconjugates and/or lipooligosaccharides (LOS) from *Neisseria lactamica* which are cross-reactive to human blood antigens.
- 3.6 This solution is considered as involving an inventive step (Article 33(3) PCT) because the prior art does not disclose nor suggests the use of LOS from *Neisseria lactamica* which are cross-reactive with human blood group antigens. On the contrary, D5 would discourage the skilled person to use these LOS antigen

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in a medicament for the prevention or treatment of a Neisseria meningitidis infection, since these blood group antigens are potential self-antigens and thus are not involved in the development of immunity against meningococci (see page 32, introduction).

- 3.7 For the same reasons as indicated above, the subject-matter of claim 12 is considered to be inventive.
- 3.8 The present application does satisfy the criterion set forth in Article 33(3) PCT and the subject-matter of claims 1-12 involves an inventive step (Rule 65(1)(2) PCT).